

REMARKS

Claim 22 has been redrafted as a product-by-process claim. The Applicant is of the opinion that this will help to more clearly define the invention and point out the differences with the prior art dextrose of Chase et al.

Further, the characteristics previously recited in claim 29 are now included in claim 22.

Claims 23 to 28, 31 and 35-36 are unamended with respect to the claims filed on April 19, 2002.

Claim 29 is deleted because its characteristics are now included in claim 1.

Claims 30, 32 and 33 are amended so as to depend on claim 22 instead of deleted claim 29.

Claims 37 to 41 were withdrawn until the time of the allowance since a rejoinder was requested.

Nonstatutory double patenting rejection

The Examiner still rejects claims 22 to 36 according to the doctrine of the obviousness-type double patenting over claims 1 to 7 of U.S. Patent 6,451,122 and therefore requests a terminal disclaimer.

The Examiner's objection is based on the obviousness-type double patenting. This means that the Examiner considers that claims 22 to 36 of the instant application are obvious over U.S. Patent No. 6,451,122.

This objection is respectfully traversed and Applicant respectfully requests reconsideration in view of the following remarks:

As now defined in the claims, the products of the invention are **dextrose hydrate in powder form** obtained by a **particular process** comprising a **wet granulation** and a **drying** steps until a **water content greater than 1%** in the final product.

This differs from the product prepared according to the method disclosed in the prior patent U.S. No. 6,451,122 wherein a **second drying step** is performed until a **water content at most equal to 1%, i.e. comprised between 0 and 1%.**

The dextrose hydrate in powder form of the instant invention defines more than a mere obvious variation of the one claimed in U.S. Patent 6,451,122 for the following reasons:

In practice, the preparation of the **anhydrous** dextrose in powder form of U.S. Patent No. 6,451,122 is much more time and cost consuming than the preparation of **dextrose hydrate** in powder form. As a matter of fact, the removal of water from dextrose powder form requires a costly and time consuming drying step.

The invention claimed in U.S. Patent 6,451,122, was based on the Applicant's discovery that dextrose in powder form according to the invention having a water content at most equal to 1% has exceptional properties of compression

and hardness. To this end a **second drying step** until a water content of at most 1% was required.

At the time of the invention the strong conditions of the second drying step were seen as a **prerequisite** to obtain such properties of hardness and compression. It was hence believed at that time that only dextrose in powder form having a water content at most equal to 1%, i.e. anhydrous would reach such hardness and compression properties.

The invention claimed in the instant application is based on the Applicant's surprising discovery that dextrose in powder form according to the invention having a water content greater than 1% shows even higher compression and hardness properties.

This discovery goes entirely against all expectations for the person skilled in the art since at the time of the instant invention it was believed that only dextrose in powder form having a water content at most equal to 1%, i.e. **anhydrous** could have high compression and hardness properties.

As a matter of fact, if it was so obvious that **hydrate** dextrose in powder form would show higher properties of hardness and compression, the Applicant would not have set forth such a costly second drying step to obtain anhydrous dextrose in powder form in order to achieve the desired properties of compression and hardness.

Note that the dextrose **hydrate** of the invention, which has a water content greater than 1%, **cannot be obtained by simply adding water** to the dextrose **anhydrous** in powder form

of U.S. 6,451,122 (which has a water content at most equal to 1%).

Adding water to the **anhydrous** dextrose in powder form of U.S. 6,451,122 would result in a solubilization of the product which would no longer be a powder.

In practice, the water molecules participate in building the crystals of the dextrose structure.

The fact that the dextrose **hydrate** of the invention has a greater water content than the **anhydrous** dextrose of the prior patent makes that the two dextroses physically differ from each other.

U.S. Patent No. 6,451,122 hence does not encompass the dextrose of the invention. Further, the dextrose hydrate of the invention cannot be seen as obvious over U.S. Patent No. 6,451,122, because this prior patent never teaches nor suggests the instant invention.

The rejection for double patenting should hence be withdrawn and a terminal disclaimer is hence not necessary.

Please note that if despite the arguments presented above, the Examiner still consider that a terminal disclaimer is required and if this is the only remaining objection, the Assignee would agree to make the appropriate terminal disclaimer.

Rejections under 35 U.S.C. 102(b)

Claims 22-36 were rejected under article 35 U.S.C. 102(b) over Chase et al. (WO 94/28181).

This rejection is respectfully traversed and reconsideration is requested for the reasons that follow:

For the record, the **dextrose hydrate in powder form** of the invention is obtained by a **wet granulation/drying method** whereas the **crystalline monohydrate dextrose** of Chase et al. is obtained by a **spray/drying method** (see page 8, last paragraph of Chase et al.). The resulting dextroses completely differ from each other.

As a result, the dextrose of the invention is a **dextrose hydrate in powder form** with a certain degree of crystallinity whereas the crystalline monohydrate dextrose of Chase et al. is **completely crystalline**.

The dextrose hydrate in powder form of the invention hence differs from the **crystalline** dextrose of Chase et al. in that it is not prepared by the same process and as a result does not have the same properties of compressibility, hardness, apparent density, mean diameter and flow grade.

The difference in compressibility has already been demonstrated with the showing provided on March 17, 2003. This showing demonstrates that the dextrose hydrate in powder form of the invention has a **higher compressibility** than the **single dextrose** disclose in table 1 in Chase et al.

In this connection, the Examiner is of the opinion that the showing is not **commensurate** with the claims because the

Applicant has performed the showing on dextrose hydrate in powder form of the invention having:

- a dextrose content at least equal to 99%,
- an alpha crystalline form content of at least 98%, and
- a water content equal to 7.6%,

while the instantly claimed dextrose has:

- a dextrose content at least equal to 98%,
- an alpha crystalline form content of at least 95%, and
- a water content greater than 1%.

First of all, the Applicant would like to point out that the dextrose of the invention assayed in the showing is fully encompassed by the claims.

Further, the selection of a dextrose content at least equal to 99%, an alpha crystalline form content of at least 98% and a water content of 7.6% for the assay of the showing was dictated by the characteristics of the single dextrose disclosed in Chase et al. in order to make a proper comparison.

For the record, the dextrose of Chase et al. has a dextrose content of 99.5%, an alpha crystalline form content of 100% and a water content of 9%.

The Applicant has hence selected a dextrose according to the invention as close as possible to the dextrose of Chase et al. in order to make the appropriate comparison with the dextrose of Chase et al.

This is why the Applicant appropriately selected such characteristics of the dextrose according to the invention assayed.

The showing is hence performed in conditions which allow a comparison with the single dextrose of Chase et al.

Furthermore, requiring assays covering the whole range of dextrose in powder form claimed would be unfair because this would be extremely time and cost consuming for the Applicant. Further, it would not be appropriate for a comparison with the single dextrose of Chase et al. having finite characteristics.

The showing clearly and undoubtedly demonstrates that the single dextrose disclosed in Chase et al. is not encompassed by the claims because for comparable dextrose content, alpha crystalline form content and water content, it has a compressibility which is lower than the claimed compressibility.

The dextrose of the invention is hence novel over the dextrose of Chase et al. and the rejection under article 35 U.S.C. 102(b) over Chase et al. (WO 94/28181) should hence be withdrawn.

Rejections under 35 U.S.C. 103(a)

Claims 22-36 were rejected under article 35 U.S.C. 103(a) over Chase et al. (WO 94/28181).

It has already been stated and evidenced that the dextrose of Chase et al. completely differs from the dextrose of the

invention because it is not obtained by the same process and as a result is not of the same nature and does not have the same properties (compressibility, hardness, apparent density, mean diameter and flow grade).

For the record, a higher compressibility value allows extended applications in the pharmaceutical field such as the filling of capsules or the preparation of hard tablets. A high compressibility is very much desired in this kind of application because it allows a direct compression.

There is neither teaching nor suggestion in Chase et al. of a dextrose hydrate in powder form obtained by the claimed method steps.

There is further neither teaching nor suggestion in Chase et al. that a dextrose hydrate in powder form prepared by such method would have a higher compressibility than a crystalline dextrose.

With its sole general knowledge, the person skilled in the art would not have arrived at the invention either.

The subject-matter of the instant claims hence cannot be seen as obvious over Chase et al.

The rejection under article 35 U.S.C. 103(a) over Chase et al. (WO 94/28181) should hence be withdrawn.

Favorable consideration and prompt allowance of these claims are respectfully requested.



Respectfully submitted

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